

MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated
RB Health (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mucinex® Fast-Max®
Cold & Flu

Drug Facts

<i>Active ingredients(in each caplet)</i>	<i>Purposes</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

temporarily relieves these common cold and flu symptoms:

- nasal congestion
- cough
- sore throat
- headache
- minor aches and pains
- sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

Questions?

1-866-MUCINEX(1-866-682-4639) You may also report side effects to this phone number.

Dist. by: RB Health (US)

Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 8 Caplet Pouch Carton

NDC 63824-575-44

MAXIMUM STRENGTH

Mucinex®

FAST-MAX®

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Guaifenesin – Expectorant • Phenylephrine HCl – Nasal Decongestant

SORE THROAT

FEVER

CHEST CONGESTION

COUGH

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

HEADACHE

BODY PAIN

ALL IN

ONE*

8 CAPLETS

(4 Pouches: 2 Caplets each)

FOR AGES 12+

MAXIMUM STRENGTH

Mucinex

FAST-MAX

COLD & FLU

MAXIMUM STRENGTH

Mucinex

FAST-MAX

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Guaifenesin – Expectorant • Phenylephrine HCl – Nasal Decongestant

NDC 63824-575-44

Drug Facts (continued)

Other information ■ Store at 20°-25°C (68°-77°F)

Inactive ingredients croscarmellose sodium, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

Questions? 1-866-MUCINEX (1-866-682-4638) You may also report side effects to this phone number.

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

©2019 RB Health
www.mucinex.com
Patents:
www.rh.com/patents

Maximum Strength per 4-hour dose
Do not take more than a total of 12 caplets in any 24-hour period.
Take only as directed

Tamper evident:
Do not use if carton is damaged or if pouch is torn or open.

3

63824-96326

6

8 CAPLETS

(4 Pouches: 2 Caplets each)



FOR AGES 12+

*Helps to relieve these symptoms day or night

8357065 013119

No Vanish Area
Lot Code &
Expiration Date Area

Directions
■ Do not take more than directed (see Overdose warning)
■ Do not take more than 12 caplets in any 24-hour period
■ Adults and children 12 years of age and over: take 2 caplets every 4 hours
■ Children under 12 years of age: do not use

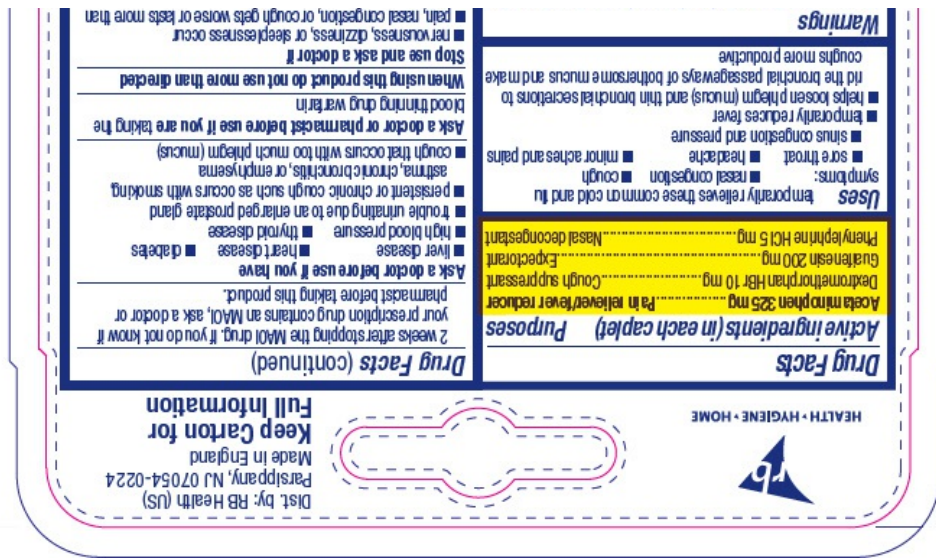
Warnings
■ If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.
■ Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Other information
■ If you do not notice any signs or symptoms.
■ If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.
■ Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Other information
■ If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.
■ Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not use
■ With any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for

Warnings
■ Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
■ more than 12 caplets in 24 hours, which is the maximum daily amount
■ with other drugs containing acetaminophen
■ 3 or more alcoholic drinks daily while using this product
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.



MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-575
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
croscarmellose sodium (UNII: M28OL1HH48)	
CROSPOLYMER, UNSPECIFIED (UNII: 2S7830E561)	
FD&C red no. 40 (UNII: WZB9127XOA)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
talc (UNII: 7SEV7J4RIU)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	MSC;VVV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-575-20	2 in 1 CARTON	07/28/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-575-44	4 in 1 CARTON	07/28/2018	
2	NDC:63824-575-72	2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/28/2018	

Labeler - RB Health (US) LLC (081049410)

Revised: 10/2019

RB Health (US) LLC